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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,023	04/12/2002	Ian L Brown	28053/37955	6243

4743 7590 09/10/2004

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EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,023	Applicant(s) BROWN ET AL.	
	Examiner Leigh C. Maier	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 and 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>June 10, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Claims 1, 3, 5, 7-10, and 26-33 have been amended. Claims 34 and 35 have been canceled. Claims 1-10 and 26-33 are pending. Claims 11-25 and 36-38 have been withdrawn as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Information Disclosure Statement

A supplemental IDS was submitted filed June 10, 2004 and has been considered. However, it was noted that the all the EP documents on the submitted search were not listed on the PTO-1449. These must be submitted and listed on a form PTO-1449 if Applicant desires that they be considered and made of record.

Claim Rejections - 35 USC § 102

Claims 1-5, 7-10, 26-28, and 30-33 are again rejected under 35 U.S.C. 102(b) as being anticipated by LAUGHLIN et al (US 5,470,839).

The claims have been amended to require replacement of at least 10% of an individual's daily carbohydrate intake to accomplish the recited methods. LAUGHLIN discloses the invention set forth in the previous Office action. The disclosed invention contains a carbohydrate component comprising 23% of high-amylose starch.

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Applicant's arguments and the declaration under 37 CFR 1.132 filed June 10, 2004 have been fully considered but they are not persuasive.

Applicant states that the term "resistant starch" refers to the *portion* of starch that is resistant to digestion. However, the examiner respectfully disagrees that this is evident from the context of the claims.

In the prosecution of claims, the examiner must assign the broadest reasonable interpretation to said claims. The interpretation relies on the text of the claims themselves, the specification, and the state of the art. In the instant case, the specification clearly states "[o]ne form of resistant starch particularly suitable for the present invention is starch *containing* resistant starch. Preferably, the starches have an amylose content of at least 40% (w/w)." (emphasis added) See page 5, lines 26-28.

Applicant cites references including BROWN et al (Food Australia, 1995) and McNAUGHT et al (WO 94/14342) to illustrate the use of the term "resistant starch" in the art. The examiner agrees that the use in BROWN is restricted to its use describing the resistant *portion* of starch, but McMAUGHT clearly demonstrates the dual nature of this term in the art. Applicant cites passages supporting its use referring to the resistant starch *content* comprised in a starch product. However, this reference also states "... it has now been found that the aforementioned *high amylose starch* is high in dietary fibre content and *is a resistant starch*." (emphasis added) See page 2, lines 22-24.

Applicant further contends that "the use of the term 'resistant starch' in conjunction with a percentage with a percentage or weight would invariably be understood . . . to refer to the resistant starch portion of that starch." The examiner can envision cases where this is true but

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respectfully disagrees that this is the case in all instances. For example, a claim reciting something to the effect of “administration of a starch comprising a resistant starch portion wherein said resistant starch constitutes 10% of an individual’s daily carbohydrate intake” would fall under this interpretation. However, the examiner maintains that the instant claim wording provides no such limiting context. Furthermore, the examiner is not saying that this wording would necessarily be supported (or not supported) by the instant specification. Even amended claim 26 (and those similar to it) do not provide such a limitation because of the broad definition of “resistant starch” in the specification.

Applicant further provides a calculation to support the contention that LAUGHLIN fails to disclose a diet in which resistant starch (limited to the resistant starch *portion*). This may be true, however, the examiner maintains that the claim allows for the interpretation of “resistant starch” to include high-amylose starch, as defined in the instant specification.

Claim Rejections - 35 USC § 103

Claims 1-10 and 26-33 are again rejected under 35 U.S.C. 103(a) as being unpatentable over LAUGHLIN et al (US 5,470,839) in view of WATANABE (US 5,300,311) and GARG (Am. J. Clin. Nutr., 1998).

The invention is as described in the previous Office action and amended as discussed above. Applicant’s arguments and the declaration under 37 CFR 1.132 filed June 10, 2004 have been fully considered but they are not persuasive.

Applicant’s arguments regarding LAUGHLIN have been addressed above.

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Applicant contends that WATANABE teaches away from the instant invention because it is drawn to the use of another type of slowly digested starch that allegedly has different taste qualities than that used by LAUGHLIN. However, that WATANABE's teaching negates the use of high amylose starch in food products is found unpersuasive. The LAUGHLIN invention was disclosed after the WATANABE teaching and found suitable for administration. In any case, arguments regarding palatability, or lack thereof, are not persuasive because the claims do not require oral administration. Finally, Applicant argues that the teachings of WATANABE would not lead one to modify the LAUGHLIN composition to arrive at the instant invention. The LAUGHLIN composition needs no modification, as discussed above. WATANABE suggests a different use (treatment of obesity) for the disclosed composition.

Applicant further argues that GARG does not teach the combination of resistant starch and monosaturated fats. Such a suggestion is not necessary for a prima facie case of obviousness. It is well settled that in the absence of unexpected results, the combination of agents having the same utility is obvious, motivated by the reasonable expectation of additive effects. As set forth in the previous Office action, resistant starch and monosaturated fats have the utility in the treatment of obesity.

Applicant further cites NOAKES (of record), arguing that this reference teaches away from the use of resistant starch in subjects who are overweight and further teaches away from the methods of (a) reducing plasma leptin concentrations; (b) lowering the risk of NIDDM; or (c) reducing postprandial glucose and/or insulin levels. The examiner respectfully disagrees with Applicant's characterization of NOAKES. However, regardless of the teachings with regard to methods (a)-(c), these methods have been inherently accomplished by the administration of the

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composition in LAUGHLIN. The claims to these methods require no particular patient population in need of treatment. The only methods with a defined patient population are those drawn to the treatment of obesity, which of course, requires an obese patient. Regarding the second full paragraph at page 17 of Applicant's remarks, the claims do not require an overweight hyperglyceridemic subject.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
August 30, 2004


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1600